



FROM: Nevada State Board of Pharmacy Inspector

SUBJECT: Self-Assessment Inspection Process

The Board of Pharmacy's established self-assessment inspection process provides management opportunity to review the standards by which the board inspects your operation. The process recognizes you as the responsible person to implement and review policies and procedures necessary to provide a quality standard of pharmaceutical services. An inspection evaluation form must be obtained from the website to self assess compliance with Nevada pharmacy law. An inspector will review the form with you and inspect your facility during ***the month listed on your Inspection Notice.***

The procedure involves the following:

1. At the ***minimum***, print and fill out the self-assessment inspection form found on the website under your designated license type. We cannot evaluate or help you if we don't know what you don't know. Retain the form and have it **readily available** in a packet so **if you are not present** when an inspector arrives, your staff can have it available.
2. An inspector will conduct a review of your operation. Observations, along with your findings, will assure understanding and compliance with Nevada law.

Failure to fill out the inspection report suggests either you are not concerned with knowing the law or complying with it.

This plan has been established as a cooperative approach to annual inspections. We would appreciate any input you may have on this joint review procedure.



ADMINISTRATION:

(the cover letter must be attached to this completed form. Circle yes for compliant and no for non compliant. You may make comments as needed)

List of all officers, directors, managers and employees available listing each of their positions/duties (NAC 639.606)?	Yes	No
Current licenses displayed (NRS 639.150,453.270,2)?	Yes	No
Written policies and procedures on prescriptive drugs including directives on the following (NAC 639.605)?	Yes	No
Procedure to identify/record/report losses or thefts?	Yes	No
Procedure to correct errors on wholesaler's inventory?	Yes	No
Procedure requiring oldest stock to be distributed first?	Yes	No
Procedure on their recall/withdrawal?	Yes	No
Requests by FDA, federal agency, board?	Yes	No
Voluntary actions by manufacturer?	Yes	No
Operation in event of strike, fire, flood or other disaster?	Yes	No
Procedure to assure outdated drugs separated/disposed of?	Yes	No
Maintenance of written records on prescriptive drugs destroyed or otherwise disposed of?	Yes	No
Policy/procedure on shipping/ delivery and receipt of prescriptive drugs?	Yes	No
Does the personnel policies/practices meet the requirements of:	Yes	No
Screening employees w/access to prescriptive drugs, education/experience (NAC 639.595, 21CFR 205.7)?	Yes	No
Screening employees w/access to controlled substances past convictions/dependency problems (21 CFR 1301.90)?	Yes	No

Inspector's comments: _____

RECORDS:

Maintains records of inventory plus receipts/dispositions of each prescription drug including (NAC 639.602):

All documents evidencing that the wholesaler ordered the drug from the supplier?	Yes	No
Invoice or other document provided to the wholesaler concerning the purchase of the drug from the supplier?	Yes	No
Copy of license of the supplier that sold the prescription drug to the wholesaler available?	Yes	No
Shipping record evidencing the shipment from supplier to wholesaler?	Yes	No
Invoice or other document received by the purchasing wholesaler for the purchase of drugs ordered?	Yes	No
Document(s) required by NAC 639.5977 that establishes reasonable assurance that the transaction is a bona fide? (see reference section for detail)	Yes	No
Maintain records for 3 years?	Yes	No
Records stored on site and immediately retrievable?	Yes	No
If offsite, ability to have the records available in 2 days?	Yes	No



Does this wholesaler have an "ongoing relationship" with his supplier (NAC 639.594)?

Written franchise, license or other agreement? Yes No

Appear on a list of distributors with which the manufacturer does business, created by manufacturer on a publicly accessible website? Yes No

Purchase of 5,000 sales units of drugs from manufacturer within 12 months preceding current transaction that wholesaler claims an ongoing relationship? Yes No

"Statement identifying prior sales of prescription drugs by a wholesaler as required by the Prescription Drug Marketing Act" (NAC 639.603): (if no manufacturer relationship exists & purchased from another wholesaler)

Includes all necessary identifying information concerning each sale in the chain of distribution? Yes No

Accompanies all prescription drugs purchased from the wholesaler? Yes No

Includes the business name and address of the person from whom the drug was purchased? Yes No

Includes the date of sale? Yes No

Includes the name of the drug? Yes No

Includes the strength of the drug? Yes No

Includes the size of the container? Yes No

Includes the number of containers? Yes No

Includes the lot number of the drug? Yes No

Includes the name of the manufacturer of the finished dosage form? Yes No

Maintained for 3 years after the expiration date of the drug? Yes No

Maintained at the wholesaler facility? Yes No

Inspector's comments: _____

STORAGE/SHIPPING:

Does facility meet general requirements (NAC 639.596)? Yes No

At least 25 foot-candle lighting? Yes No

Storage area facilitates access to prescription drugs? Yes No

Maintained in a clean and orderly condition? Yes No

Free of insects, rodents, birds or vermin? Yes No

Secure against access by unauthorized persons? Yes No

Equipped with an alarm system to detect entry after business hours? Yes No

Alarm Provider? Yes No

Storage conditions comply w/the US Pharmacopoeia (NAC 639.598)?

Temperature record maintained (59-86°F)? Yes No

Separation/disposal of prescription drugs (NAC 639.601)? Yes No

Separate area for storage outdated/damaged/adulterated drugs? Yes No

Are returned drugs sold to other purchasers? Yes No

Has an examination/testing assured drugs are not expired/adulterated? Yes No

Outdated/mislabeled/adulterated drugs in stock (NAC 639.605)? Yes No

Examination of prescription drugs in shipment (NAC 639.599)? Yes No

Incoming shipments examined for damage/contamination? Yes No

Outgoing shipments examined for damage/contamination? Yes No



Do vehicles, used for transport of prescription drugs, meet cleanliness, temperature and security standards?

Yes No

Inspector's comments:

SECURITY: (NAC 639.597)

Access to the facility kept to a minimum and well-controlled?	Yes	No
Outside perimeter properly lighted?	Yes	No
Does the facility distribute controlled substances? (NAC 639.597) (if no skip section)	Yes	No
Access to controlled substances area limited to authorized persons?	Yes	No
Does the facility have a controlled substance cage?	Yes	No
Steel, at least 10 gauge in thickness?	Yes	No
Openings not more than 2 1/2" wide?	Yes	No
Steel post of at least 1" diameter?	Yes	No
Cage ceiling?	Yes	No
Extended to structural ceiling?	Yes	No
Cage walls at least 14' in height (ceiling may be screened with lighter gauge steel)?	Yes	No
Cage walls under 14' (ceiling must be covered with at least 10 gauge steel)?	Yes	No
Access limited to staff responsible for security?	Yes	No
Separate alarm system to law enforcement/security agency?	Yes	No
Alternative security plan authorized by Secretary?	Yes	No

REMARKS

Your wholesale/manufacturing business has been inspected by an agent of the Nevada State Board of Pharmacy. The results of this inspection are noted above. Conditions that are unsatisfactory must be corrected within the time frames stated to ensure compliance with the laws/regulations governing wholesaler/manufacturer businesses.

I acknowledge the noted unsatisfactory conditions have been explained to me and I have received a copy of this inspection report.

Licensee Printed Name

Licensee Signature

Board Inspector

Dated

Dated

Reference

NAC 639.5977 Prescription drugs: Sale to purchasing wholesaler. ([NRS 639.070](#), [639.595](#))

1. For each sale of a prescription drug to a purchasing wholesaler, the wholesaler must, as a reasonable assurance that the purchasing wholesaler is in compliance with the provisions of subparagraph (2) of paragraph (c) of subsection 2 of [NRS 639.595](#):

(a) Before the sale of the prescription drug, obtain from the purchasing wholesaler a written statement that contains a representation by the purchasing wholesaler that, for transactions which occur in this State, the purchasing wholesaler will only sell the prescription drug to a pharmacy or practitioner;

(b) Possess written correspondence between the wholesaler and the purchasing wholesaler or between the purchasing wholesaler and other purchasers that evidences the compliance by the purchasing wholesaler with the provisions of subparagraph (2) of paragraph (c) of subsection 2 of [NRS 639.595](#); and

(c) Ensure that the following statement is written on the face of the invoice or other document which evidences the sale and on the face of any "Statement Identifying Prior Sales of Prescription Drugs by Wholesalers Required by the Prescription Drug Marketing Act" described in [NAC 639.603](#) that accompanied the sale of the prescription drug printed in all capital letters and in at least 10-point type:

NEVADA LAW REQUIRES THAT YOU MUST SELL THE PRESCRIPTION DRUGS SOLD TO YOU AS SET FORTH IN THIS DOCUMENT ONLY TO PHARMACIES OR PRACTITIONERS. THE SALE OF ANY OF THE PRESCRIPTION DRUGS SOLD TO YOU AS SET FORTH IN THIS DOCUMENT TO ANY PERSON OR BUSINESS OTHER THAN A PHARMACY OR PRACTITIONER WILL RESULT IN A TERMINATION OF FUTURE SALES AND MAY SUBJECT YOU TO OTHER PENALTIES AS PRESCRIBED BY LAW.

2. For the purposes of this section, the Board will consider the sale by a wholesaler to a purchasing wholesaler whose sole function is to distribute prescription drugs to pharmacies under common ownership with the purchasing wholesaler to be a sale to a pharmacy.

(Added to NAC by Bd. of Pharmacy by R049-04, eff. 2-28-2005)

NAC 639.5935 Representative of wholesaler: General requirements; exceptions; approval; enforcement. ([NRS 639.070](#), [639.100](#))

1. Except as otherwise provided in this subsection, an applicant for a license, or a licensee with a license, to operate as a wholesaler shall designate at least one natural person to serve as the representative of the wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a wholesaler pursuant to this section unless the Executive Secretary determines that the designated natural person meets the qualifications set forth in subsection 2 and approves that natural person to be the designated representative of the wholesaler. The requirement to designate a representative set forth in this subsection does not apply to:

- (a) An applicant that is a publicly traded corporation; or
- (b) An applicant in which a majority interest of the applicant is owned by a pharmacist who is:
 - (1) Licensed by the Board;
 - (2) A resident of this State; and
 - (3) Not an owner of any interest in a pharmacy licensed by the Board.

2. Except as otherwise provided in subsection 3, the Board will approve a natural person as the representative of a wholesaler if the applicant for a license to operate as a wholesaler or the licensee presents proof satisfactory to the Executive Secretary that the natural person:

(a) Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(b) Has received a score of at least 75 percent on an examination given by the Board regarding federal and state laws and wholesaler practices; and

(c) Is at least 21 years of age.

3. The Board may, based upon any of the grounds set forth in [NRS 639.210](#), refuse to approve a natural person for service as the representative of a wholesaler, regardless of whether the person is otherwise qualified.

4. A representative of a wholesaler designated pursuant to this section:

(a) Must be actively involved in and aware of the actual daily operation of the wholesaler;

(b) Must be employed full-time in a managerial level position with the wholesaler;

(c) Must be physically present at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leave, vacation leave and other authorized absences; and

(d) May serve in this representative capacity for only one wholesaler at a time.

5. A wholesaler that is required to designate a natural person as its representative pursuant to this section shall not open or operate a facility unless that representative is actually employed full-time in the operation of the wholesaler and is physically present at the facility of the wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a wholesaler leaves the employ of the wholesaler, thus leaving the wholesaler without a representative in violation of this section, the wholesaler shall:

(a) Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the wholesaler; and

(b) Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the wholesaler has left the employ of the wholesaler.

6. Before a wholesaler that is in violation of this section because the natural person designated as the representative of the wholesaler left the employ of the wholesaler may continue conducting business:

(a) The wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the wholesaler; and

(b) The Executive Secretary must approve the natural person so designated.

7. A wholesaler that operates without a representative in violation of this section is subject to the immediate suspension of its license until it employs a qualified natural person to be its representative. The Executive Secretary may take such action as deemed necessary to secure the facility of the wholesaler and to ensure that the wholesaler does not conduct business during the period of the suspension.